DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 1998

David P. Mayou
Vice-President
Benson Medical Instruments Company
2344 Nicollet Avenue, Suite 150
Minneapolis, MN 55404

Re: K981439
CCA-200 (Computer Controlled Audiometer
Dated: March 19, 1998
Received: April 21, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

Dear Mr. Mayou:

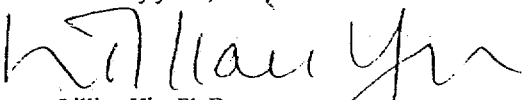
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Acf include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981429 K981439

Device Name: CCA-200

Indications For Use:

The CCA-200 Computer Controlled Audiometer is an air conduction audiometer designed to provide automatic hearing testing. A series of tones is presented by the CCA-200 through a TDH-39 headset to the test subject. The test subject then presses a hand switch to indicate to the CCA-200 that the tone has been heard. The CCA-200 proceeds with the hearing test using the Modified Hughson-Westlake method of hearing testing, and records the subject's responses. The resultant data are available to print on an external printer connected to the control computer or to store in the computer.

The CCA-200 can perform its function only on command from a control computer. The computer monitor displays the setup and control screens that are used to perform the test functions. An IBM compatible computer with a 486DX2-50 or processor, running Windows 95 or Windows NT, is required. Control of the CCA-200 is handled through the RS232 serial port. The computer is not included with the CCA-200.

The CCA-200 is designed for use in test environments where multiple automatic hearing tests are controlled from a single computer. The CCA-200 has a range of options for both computer interfacing and automatic testing, such as multilingual voice instructions. These options are selected using a setup screen on the computer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981439

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)